

1 that was not approved by the FDA in this case and was not  
2 specifically approved for diagnosing AIDS wasting.

3 So did it have any actual benefit to patients other  
4 than attempting to diagnose AIDS wasting? For these purposes,  
5 no, your Honor.

6 THE COURT: Did it not diagnose AIDS wasting -- did  
7 it diagnose AIDS wasting as redefined?

8 MS. CARMODY: As redefined.

9 THE COURT: And the software packages that went  
10 into the program were designed -- were fraudulent altogether or  
11 were the results manipulated? It's something that wasn't clear  
12 to me.

13 MS. CARMODY: Both, your Honor.

14 THE COURT: Okay.

15 MS. CARMODY: What happened was that in -- when the  
16 company knew that they were losing -- basically, to define --  
17 AIDS wasting is a condition that you can see immediately. In  
18 the 1980s and the early '90s when people were suffering from  
19 HIV and AIDS, you can see the gaunt look, the holocaust  
20 survivor look, and that's AIDS wasting; you can measure that on  
21 a scale.

22 You can measure --

23 THE COURT: You mean a regular bathroom scale?

24 MS. CARMODY: Right. Because the question was  
25 whether these patients had an intentional weight loss of more

1 than ten percent or preferential weight loss of lean body mass  
2 over fat, so that people were losing the stuff that really held  
3 your body together and made it healthy, organs and that sort of  
4 thing.

5           So that when the company knew that they didn't have  
6 that quantity of patients that had lost more than ten percent  
7 of their weight loss or more than 90 -- or were lower than 90  
8 percent of ideal body weight, and it was an unintentional  
9 weight loss -- people can lose weight for a lot of different  
10 reasons that have nothing to do with this specific issue,  
11 people can lose weight because they have a form of cancer or  
12 they have an infection or they're not eating right. This is  
13 unintentional weight loss. So people that are losing weight,  
14 don't want to, and can't figure out why they're doing that. So  
15 that was one issue.

16           But when the protease inhibitors came on the market  
17 in the late 1990s -- 1996, just at the same time, they treated  
18 the virus itself, the HIV virus itself, which then resulted in  
19 that wasting condition essentially declining and almost  
20 disappearing. Although there is a small percentage of patients  
21 even today that are resistant to those drugs or for some other  
22 reason do not respond to the HAART cocktail; and, therefore, a  
23 small patient population for whom this can be a life saving  
24 drug.

25           THE COURT: So the software that the company

1 developed would work for these folks, the people who -- who --  
2 for whom the protease inhibitors will not work? Will it really  
3 work to give them useful information? Or is it simply the  
4 software is just a sham?

5 MS. CARMODY: It's a sham, your Honor. It was  
6 always a sham.

7 The patients that really need the drug were very  
8 easy to diagnose, and the company in its documents describe  
9 patients as severe wasting, body cell mass wasting, and the --  
10 and so that they made clear distinctions between a patient with  
11 severe wasting and body cell mass wasting.

12 Body cell mass wasting could only be diagnosed  
13 using the BIA machine and was never recognized in any respect  
14 by the FDA, either as an appropriate criteria for the patient  
15 population on whom this drug was tested in the FDA process of  
16 the approval process, both pre -- before receiving accelerated  
17 approval, and in the phase four confirmatory trials. The FDA  
18 never recognized that as a valid criteria for determining  
19 whether or not Serostim was either safe or efficacious.

20 So that criteria was never within the contemplation  
21 of the FDA in putting this drug on the market.

22 (Discussion off the record.)

23 MS. CARMODY: And with respect to going beyond that  
24 condition which doctors could readily diagnose and see, the  
25 only way to expand the definition of the disease state was to

1 use this device with respect to body cell mass wasting.

2 (Discussion off the record.)

3 THE COURT: Okay.

4 MS. CARMODY: Body cell mass, in terms of the  
5 criteria the FDA looked at and the company looked at in the  
6 testing trials, they looked at lean body mass and never looked  
7 at body cell mass. And body cell mass is not something that  
8 can be seen, it's the only measure -- if there is a measure,  
9 and there's a lot of difference of opinion even today in the  
10 medical community whether or not there is any way to accurately  
11 measure body cell mass in any individual.

12 The software that the company developed with and  
13 through RJL -- and RJL is a very small, less than ten person  
14 operation just outside of Detroit. It was one of the few  
15 manufacturers of this kind of device in the country, and they  
16 went -- the company went to RJL as early as 1995 and was  
17 talking about the BIA device; but the conspiracy really began  
18 in 1996 when they changed the software that was used to  
19 accompany the BIA device. And there were four different kinds  
20 of software --

21 THE COURT: Did RJL do that software?

22 MS. CARMODY: RJL worked with the company to  
23 develop the software.

24 THE COURT: Developed the software.

25 Is RJL then a co-conspirator here?

1 MS. CARMODY: RJL is a co-conspirator here, and  
2 they have been charged in an information in a related case.  
3 The company and the president have both pled guilty to an  
4 information charging similar -- charging essentially this  
5 conspiracy last April, and they're due for sentencing in  
6 February of 2006.

7 THE COURT: Okay.

8 MS. CARMODY: They developed in 1994 the FNA  
9 software.

10 And I won't go into the particulars of each  
11 software. I'll rely on the sentencing memorandum for that.

12 But the important parts of this particular  
13 development, because it was the first in the long line of  
14 development, was that the prediction equation that -- and in  
15 order to get the readings from the BIA device, they have to put  
16 the readings of reactants and resistance into the computer  
17 software using a predictive equation based upon a particular  
18 patient or population to determine how the person that's being  
19 tested measured up to some kind of a normal or otherwise  
20 population.

21 The predictive equation is used to estimate the BCM  
22 based upon the measurements of total body potassium, that was  
23 in the FNA software. That's a different base than was used in  
24 the prior device that the RJL had had approved by the FDA.

25 They also used a different patient population, a

1 different database, this time consisting of about 332 humans  
2 who were either healthy or had tested for HIV. Very different  
3 patient population than the device had been approved for in the  
4 1980s.

5           So RJL, together with Serono -- and there were  
6 several people from Serono, people that worked in the marketing  
7 department as well as people in the medical affairs department  
8 that worked together to develop this computer software to see  
9 whether or not they could determine body cell mass and whether  
10 or not that could be used as a criteria to determine whether  
11 someone was suffering from AIDS.

12           But this patient -- this equation, this device with  
13 a different equation and a different database, was also being  
14 used for a different purpose than the device was being used in  
15 the 1980s; and that was specifically to determine whether  
16 someone had the redefined AIDS wasting. And that, in fact, was  
17 the new and intended use that is the basis for the crime with  
18 respect --

19           THE COURT: Not approved by the FDA.

20           MS. CARMODY: It was never approved -- they never  
21 even applied for any kind of approval from the FDA.

22           So they went from FNA software that was being  
23 used -- and, by the way, your Honor, not only were they using  
24 it to define within the company, but what they did with the  
25 devices was they sent the devices to physicians. The company

1 had a different progression with respect to the devices. The  
2 devices themselves cost about -- on retail about \$4,500,  
3 \$4,900.

4 The company made a major purchase where they paid  
5 about \$2,500 for each device, and they wanted first to lease it  
6 or to sell it to doctors. They didn't get enough interest in  
7 doctors of leasing it and selling it, so they then decided to  
8 give it away to doctors, because they had to put these devices  
9 in the doctors' offices in order for the doctors to go beyond  
10 that scale into body cell mass wasting.

11 So what they also did was train their employees not  
12 only on how to do the tests, and the employees went in and both  
13 showed doctors and their staffs how to perform the tests, but  
14 also did the tests themselves.

15 The second software that was developed between the  
16 company and RJL was in about 1998 it incorporated the same  
17 equation that was used in the FNA software, but they measured  
18 it against a different population base so that they would get  
19 different results. Because this was a database of humans  
20 derived from something called the National Health and Nutrition  
21 Examination Survey, often referred to as NHANES; and this new  
22 software which was also used by company employees and  
23 disseminated to doctors' offices, and this is throughout the  
24 United States, was required premarket approval from the FDA  
25 before its introduction, and no such approval was either sought

1 or obtained.

2           The next software was developed in about August of  
3 1999, and that's the SomaScan software. And I would point out  
4 one thing, your Honor, because I think it's important. We did  
5 submit as part of the offense conduct, it's not public, but it  
6 is referred to in the presentence report, the summary of the  
7 total Medicaid reimbursement, not just for Medicaid but for  
8 other federal programs, and it shows the sales over the years.

9           And your Honor will notice that the sales increased  
10 in 1998 but went up exponentially in 1999 and 2000. And this  
11 was about the same time of the introduction of the SomaScan  
12 software was being developed and disseminated to the employees  
13 of Serono for their use and for doctors' use.

14           After this particular software, in addition to  
15 using that same predictive equation again for estimating body  
16 cell mass, among other things, it further computed the  
17 purported precise ideal amounts for each of these measurements  
18 for individual test subjects and compared them to this NHANES  
19 database. But the key here is they eliminated any standard  
20 deviation from its calculations, which absolutely skewed the  
21 results.

22           The results were so skewed that when employees were  
23 given the software, they were told to retest patients so that  
24 when they retested patients who had already tested and not  
25 shown to be wasting, these new patients would actually -- were



1 actually shown to have been wasted.

2 This was also a new and intended use, and it  
3 required premarket approval from the FDA before introduction  
4 into interstate commerce, and no approval was sought or  
5 obtained.

6 And, finally, the fourth variation on the software  
7 was Cyprus 1.2 condensed. It was introduced in February of  
8 2000. And during the period of time, especially, in  
9 particular, in 1999, the problems with the SomaScan software  
10 was something that was a priority at the company. This was  
11 something that was so out of whack, so to speak, with the  
12 results that they had received previously, that it was a real  
13 focus of attention.

14 So that they tried, again, to revise the software  
15 to determine whether or not they could come up with anything  
16 that would be the gold standard or validated results with  
17 respect to these tests.

18 So Cyprus 1.2 then computed purported normal  
19 amounts and normal ranges, again, using the Z equation, as we  
20 call it; and this, again -- a portion of the NHANES database  
21 but a different patient population in that NHANES database.

22 This was also a new and intended use. It required  
23 premarket approval, and no such approval was either submitted  
24 or obtained.

25 What the company -- and I've already alluded to

1 it -- was doing with this software, which was its primary  
2 marketing tool, and one particular document that stands out in  
3 my mind in terms of company documents was one e-mail done by  
4 the company's medical director that said -- referred to how  
5 tests ought to be performed and said although we don't market  
6 solely using the BIA test -- so even the medical affairs people  
7 in the company, as well as the marketing and sales people, knew  
8 that this device was being used to market its product.

9           The only purpose of this device was to redefine and  
10 expand the definition of AIDS wasting into an area that the FDA  
11 had never approved. And they went as far as to measure amounts  
12 of their employees' time as to how much time they were spending  
13 doing BIAs; and, in particular, used something called the BIA  
14 hit rate, which is measuring how many prescriptions they would  
15 obtain after doing how many BIA tests. So that they were  
16 measuring the success of using this tool that had never been  
17 approved by the FDA for the purpose for which they were using  
18 it.

19           THE COURT: And the point of this, as I understand  
20 it, the government to be charging is the point of this device  
21 is to show people that, notwithstanding how they looked, what  
22 they -- the fact that they might be gaining weight, they still  
23 had body wasting and they needed the drug.

24           MS. CARMODY: Exactly, your Honor.

25           THE COURT: And then they go out and buy the drug.

1 MS. CARMODY: Exactly, your Honor.

2 Now, the primary -- and this is important  
3 particularly with respect to the Court's comment at the  
4 beginning of the hearing today, the primary customer for this  
5 drug were the state Medicare agencies.

6 They were the ones who had to approve the  
7 reimbursement, and the primary -- many of the people with AIDS  
8 and HIV, as the Court so accurately pointed out, were the most  
9 vulnerable people in our health care system; people that had  
10 HIV and AIDS; people that didn't have the means to have their  
11 own health insurance; and people that were really at the mercy  
12 of our health care system. And they got their drugs primarily  
13 through the Medicaid systems, through the state that were  
14 partially funded by the federal government.

15 And, by the way, the state Medicaid agencies for  
16 the record are federal health care programs as defined in 18  
17 USC section 24.

18 So these state Medicaid agencies had to approve the  
19 drug. The drug, as we mentioned and the Court mentioned, is a  
20 very expensive drug, \$21,000 for a 12-week course of treatment.

21 The company aggressively marketed and lobbied the  
22 state Medicaid agencies, not just on putting the drug on the  
23 formulary, but providing for them the criteria for  
24 reimbursement; creating treatment guidelines; using experts  
25 that were friends of the company, so to speak, to come

1 together, thought leaders, people respected in their field, to  
2 develop guidelines for them to then take to state Medicaid  
3 agencies so that the state Medicaid agencies would use as a  
4 criteria for reimbursement the BIA test.

5 And they were very successful at doing this; and  
6 they were very successful, in particular, in doing it in the  
7 top two states that had the highest number of AIDS patients in  
8 the country and paid the most for the drug, and that was both  
9 California and Florida.

10 So they went to the state Medicaid agencies. We've  
11 spoken to the witnesses at the state Medicaid agencies to  
12 determine, you know, how those BIA tests were used, and how the  
13 criteria was changed to accommodate this BCM wasting.

14 One of the -- and I know we've talked about this,  
15 but one of the -- a couple of the tools that the company used  
16 to determine or to tell their sales force to talk to people  
17 about was -- and, particularly, referring back to your comments  
18 a moment ago that you couldn't tell somebody was wasting was a  
19 difference -- looking at a muffin, you can't tell the  
20 difference between a low fat and a fat-free muffin, but there's  
21 a difference in the body composition of that muffin.

22 THE COURT: May I interrupt you just a minute?  
23 Because I think -- I don't want to have you tell the whole  
24 story and not get to the other part of the case. I'm not sure  
25 you haven't covered the area of the conspiracy and the fact

1 that you have an adulterated medical device by saying none of  
2 these use the --

3 MS. CARMODY: Were approved by the FDA.

4 THE COURT: -- were approved. I've read the  
5 details. I'm not sure you need to add all the details you're  
6 about to add.

7 If you think so, you can, but I'm not sure I  
8 haven't heard at least the elements I need to determine;  
9 namely, the conspiracy and the adulterated device. So I'm  
10 suggesting you might want to go on to the second count. Maybe  
11 you've already covered the second count.

12 MS. CARMODY: I've covered it to a small point,  
13 your Honor, and I will just refer, if there's anything that the  
14 Court needs further, to the PSR and the sentencing memorandum  
15 with respect to count one.

16 With respect to count two, I'll state it briefly.  
17 In early 1999, sales were down with the company. They needed  
18 to kick start sales for a number of reasons, including the fact  
19 that high-level officials in the company were coming from  
20 Switzerland to the United States for a major meeting. There  
21 was an international conference on nutrition and HIV infection  
22 that was held in Cannes, France on a semi-annual basis. This  
23 was the third conference. It was to be held in April of 1999.

24 And in March -- March 1 of 1999, at the Boston  
25 Harbor Hotel here in Boston, an emergency meeting was held.

1 Regional directors were coming for another purpose, but they  
2 were also asked to come to an emergency meeting that was held  
3 by the top management of the unit of Serono Labs that  
4 specifically was responsible for the Serostim sales -- and  
5 that's the metabolic and immune therapy unit at the time, often  
6 called M&IT -- and the top management, which included the vice  
7 president of sales, who was Mary Stewart, and the vice  
8 president of marketing, who was John Bruens, both of them are  
9 individuals who have been indicted in a related case on this  
10 specific conspiracy.

11 Serono Labs knew that the offering and inducement  
12 to a physician to get them to refer a patient or write  
13 prescriptions for Serostim so they would then take it to a  
14 pharmacy and had it filled, including at a Medicaid agency,  
15 they knew that was wrong. They had had training on kickbacks,  
16 so they knew that.

17 But at the end of February of 1999, they were only  
18 meeting 80 percent of their sales goal. They needed to kick  
19 start sales. So on March 1st, they had a meeting. The vice  
20 president of marketing, the vice president of sales, and other  
21 top management called together the regional directors. The  
22 country at that time for its sales purposes were divided into  
23 six regions, each led by a regional director.

24 So they pulled in those regional directors, one of  
25 whom was Adam Stupak, who has pled guilty in a related case and

1 is awaiting sentencing; one of whom is a relator in a civil  
2 case; and spoke to the regional directors about kick starting  
3 sales, and, in particular, targeting high prescribers to go to  
4 the conference in Cannes in return for writing -- at that time  
5 the plan was writing 30 scripts for the trip.

6           The regional directors then, taking their orders  
7 from top management, went out and some of the regional  
8 directors did exactly what their top management told them to  
9 do. And, in particular, Adam Stupak would testify that he went  
10 out and offered -- made the offer to three doctors in New York  
11 and the doctors not just in New York but in other areas of the  
12 country, some of them accepted it, some of them rejected it,  
13 and some of them, you know, simply walked away from it.

14           Some of them accepted it and went, some of them  
15 didn't accept it at first and went. But the bottom line was  
16 that two -- at least two of the doctors told their sales  
17 representatives that this was not an appropriate offer and that  
18 it was -- calling it -- so much as calling it a bribe.

19           And that information even went back to top  
20 management through the regional directors and still they  
21 continued on with the program.

22           Approximately 20 doctors were offered the trip, 13  
23 accepted the trip.

24           I think that should be sufficient on count two,  
25 your Honor.

1 THE COURT: Well, let me ask you. I have a  
2 question about count two, and the question is: Who are the  
3 conspirators?

4 MS. CARMODY: The conspirators were the executive  
5 vice president who led the marketing -- the Serostim business  
6 unit, but in particular, the conspirators were Mary Stewart,  
7 who was the vice president of sales; John Bruens, the vice  
8 president of marketing; the regional directors; in particular  
9 Adam Stupak; and the regional directors that are charged in a  
10 related indictment, Marc Sirockman and Kimberly -- Melissa  
11 Vaughn, excuse me.

12 THE COURT: Help me understand. These people all  
13 work for the corporation.

14 MS. CARMODY: Yes, your Honor.

15 THE COURT: So they are agents of the corporation.

16 MS. CARMODY: Yes, your Honor.

17 THE COURT: The corporation acting only through its  
18 agents.

19 The corporation is a co-conspirator -- is a  
20 conspirator. Are you saying that the individual people who  
21 acted for the corporation are also the conspirators? You  
22 follow me?

23 MS. CARMODY: I can tell you how the corporation  
24 acted to -- your Honor, I think what you're asking me is are  
25 they acting ultra vires?



1 THE COURT: No, that's not what I'm asking.

2 I'm asking -- the defendant before me is the  
3 corporation.

4 MS. CARMODY: Right.

5 THE COURT: And my question is, the defendant is  
6 charged with conspiracy, there have to be two people, two  
7 conspirators. The corporation is a conspirator, and I'm asking  
8 you who is the other conspirator or the other conspirators?  
9 And your answer initially were these people who work for the  
10 corporation; and as to that I'm just asking you if those people  
11 can be conspirators, since they were, in fact, acting for the  
12 corporation?

13 MS. CARMODY: Yes, they can, I think, your Honor.

14 THE COURT: Well, you think -- I mean, I don't --  
15 is that right? Can they be conspirators? Maybe they can, I  
16 guess I don't -- I guess I'm not saying they can't, I just need  
17 to know that.

18 Mr. Depippo, you represent the corporation. I just  
19 need to understand this legal question. I'm asking a legal  
20 question. I'm asking to both of you a legal question.

21 MR. DEPIPPPO: Judge, I always understood the  
22 conspiracy to involve the corporation and certain physicians.  
23 There are a number of people outside of the corporation --

24 THE COURT: Perhaps they are. The physicians, I  
25 assume, were the offerees. The conspiracy is charged as a

1 conspiracy to offer. So the question, even with respect -- I  
2 thought about your position. The question I have is whether a  
3 physician -- perhaps you're right, perhaps a person who is the  
4 offeree can be a co-conspirator, but only -- I assume only can  
5 be the person who accepts the offer.

6 MR. DEPIPPPO: Right. And I think they've  
7 articulated, at least the way I've always read count two, is  
8 that certain physicians did accept the offer.

9 THE COURT: I understand. But you understand the  
10 conspiracy crime is complete when -- at the conspiracy level,  
11 not when the crime is carried out.

12 MR. DEPIPPPO: When the agreement is made.

13 THE COURT: The agreement. And the agreement is to  
14 do an illegal act. The illegal act charged is offering to pay  
15 illegal remuneration. As a kind of intellectual matter, I'm  
16 having trouble understanding the offeree conspiring to offer.

17 MS. CARMODY: I think I can help.

18 THE COURT: Okay.

19 MS. CARMODY: Corporate policy, the top management,  
20 the vice president of sales and marketing held a meeting in  
21 Boston where they told regional directors to go and make this  
22 offer.

23 THE COURT: Yes.

24 MS. CARMODY: Now, they were employees of the  
25 corporation, but they're also individuals. They could choose,

1 that was their choice, the individual regional directors, to  
2 participate in this conspiracy or not. And, in fact, that was  
3 the case. Some regional directors went out and joined the  
4 conspiracy, joined the agreement and went out and made the  
5 offers to doctors and made the payments. Not every regional  
6 director has been charged in this case nor is it alleged that  
7 every regional director participated.

8 THE COURT: I see.

9 MS. CARMODY: There were others that recognized the  
10 wrongness of this corporate policy and decided and determined  
11 not to participate in it.

12 THE COURT: Okay. Let me understand now. So the  
13 corporation, acting through its executives, the people you  
14 identified, the exec --

15 MS. CARMODY: John Bruens and Mary Stewart, among  
16 others.

17 THE COURT: Who are they?

18 MS. CARMODY: They were the vice president of sales  
19 and the vice president of marketing.

20 THE COURT: So they act for the corporation.

21 MS. CARMODY: Yes.

22 THE COURT: They go to employees and they say go  
23 out and make these offers.

24 The people whom they direct, understanding,  
25 presumably, this is illegal to do this, agree with the

1 corporation through its executives to go out and make these  
2 offers.

3 MS. CARMODY: That's correct.

4 THE COURT: Okay. And so you say that when they  
5 agree, they're acting as individuals, not as agents of the  
6 corporation.

7 MS. CARMODY: Because they're not corporate  
8 officers; they're employees.

9 THE COURT: Okay. All right.

10 MS. CARMODY: Okay.

11 THE COURT: All right.

12 MS. CARMODY: Does the Court have any other  
13 question on count two?

14 THE COURT: I don't think so.

15 MS. CARMODY: Okay. So I'll refer any other facts  
16 that I have not stated in open court to the sentencing  
17 memorandum incorporate that, and that would be our evidence on  
18 count one and count two, your Honor.

19 THE COURT: Mr. Depippo, do you have anything you  
20 want to add? This is the government's presentation.

21 You're satisfied with the explanation given to me  
22 by Ms. Carmody that the conspiracy was the corporation  
23 conspiring with certain of its employees to violate this  
24 statute?

25 MR. DEPIPPPO: Judge, I would also -- and again, the

1 way I always read that was that would include --

2 THE COURT: Doctors.

3 MR. DEPIPPO: Would include doctors.

4 THE COURT: Well, I'll include them for this  
5 purpose, because I am persuaded by the employees. The doctors  
6 I have a less comfort with, because, as I say, the doctors --  
7 the charge is conspiring to offer. This is not conspiring  
8 to -- it's not a bribery conspiracy in the sense that -- maybe  
9 it is, but I'm just looking at the language, the conspiracy to  
10 offer. Maybe the offeree can be a conspirator.

11 MR. DEPIPPO: I was going to say I just read it  
12 broadly, it's a conspiracy to violate the anti-kickback  
13 statute, which certainly can be violated by a physician who  
14 agrees to accept the payment.

15 THE COURT: All right. Fair enough. It's just the  
16 language of the information was a little -- I had a little  
17 concern with the use of conspiracy, language of the  
18 information.

19 Let me ask you, Mr. Gunning -- please, if you'll  
20 stand again -- did you hear all the things that Ms. Carmody  
21 said?

22 MR. GUNNING: I did.

23 THE COURT: Do you have any questions about  
24 anything she said?

25 MR. GUNNING: I don't.

1 THE COURT: Do you agree; that is to say, do you  
2 disagree with anything she said?

3 MR. GUNNING: Yes. We don't agree with all of the  
4 facts in the information or the sentencing memo, but I did  
5 understand your explanation of the material elements of the  
6 crimes, and we agree to the facts that would support those  
7 elements.

8 THE COURT: You have the government's sentencing  
9 memorandum?

10 MR. GUNNING: As of yesterday afternoon, yes.

11 THE COURT: And you read it?

12 MR. GUNNING: Yes.

13 THE COURT: What facts do you disagree with as  
14 recited by Ms. Carmody and in the memorandum?

15 MR. GUNNING: I can try to give some examples, but  
16 I can't give you a laundry list --

17 THE COURT: Well, I ask this question, because,  
18 depending on what facts you disagree with, you may be  
19 disagreeing with the crime that was committed. It may be that  
20 you're talking details, maybe this sale wasn't made, that sale  
21 wasn't made, but some sales were made. Maybe there were three  
22 software packages, not four, details of that kind. If that's  
23 the thing you're talking about, okay -- I just need to know,  
24 because I need to know whether you are actually admitting to  
25 these crimes.

1 MR. GUNNING: I think it's detail, I think if we go  
2 on to some of the things we agree with --

3 THE COURT: Maybe that would be helpful. Yes, that  
4 would be helpful.

5 MR. GUNNING: I guess in the late 1990s we agree  
6 that Serono Labs with RJL introduced the BIA machines that  
7 contain software that was not approved by the FDA.

8 THE COURT: Okay. All right. And how about with  
9 respect to count two?

10 MR. GUNNING: I guess as to count two, Serono  
11 Laboratories also agreed to make payments to certain physicians  
12 in the form of a trip to Cannes, France to attend a medical  
13 conference.

14 THE COURT: And this agreement was with the  
15 employees, the regional directors --

16 MR. GUNNING: The payments were made to physicians.

17 THE COURT: The payments were made, but who is it  
18 that you agreed with the regional directors that they should go  
19 out and make these offers?

20 MR. GUNNING: I guess on this point, at least as I  
21 understand the information, it's a conspiracy to offer and pay  
22 remuneration to physicians.

23 THE COURT: All right. Then let me ask you it this  
24 way: Ms. Carmody explained what happened. There was a  
25 meeting, two executives from the company came, and they

1 instructed regional directors to go out to get employees to  
2 make these offers. Have I summarized what you said?

3 MS. CARMODY: Yes, your Honor.

4 THE COURT: Do you agree with that much?

5 MR. GUNNING: Can I consult just for a minute?

6 THE COURT: You certainly may.

7 (Discussion off the record.)

8 MR. GUNNING: I guess we acknowledge that Adam  
9 Stupak, one of our former employees, has pled guilty. We also  
10 acknowledge -- understand that the other individuals that have  
11 been charged are contesting their guilt.

12 THE COURT: Well, that's not the same thing as  
13 agreeing that the corporation -- Ms. Carmody said that the two  
14 executives of the corporation had a meeting at the Boston  
15 Harbor Hotel and instructed or directed regional directors to  
16 go out or have people working for the regional directors to go  
17 out and make offers to physicians that if they were to  
18 prescribe the drug -- Ms. Carmody?

19 MS. CARMODY: Yes, your Honor.

20 THE COURT: -- to prescribe the drug in sufficient  
21 numbers, 30, I think, they would get this trip to this  
22 conference in France; and that 20 of such offers were made  
23 pursuant to this direction, and 13 people went to that  
24 conference. I think that's what you said.

25 MS. CARMODY: Yes, your Honor.



1 THE COURT: All right. Does the company agree --  
2 does the company admit that that happened?

3 (Mr. Gunning conferred with counsel.)

4 MR. GUNNING: The numbers and the details are -- I  
5 have a hard time confirming those facts. We do know that some  
6 offers were made and some payments were made to physicians in  
7 order to attend a conference in Cannes, France.

8 THE COURT: Work with me, Mr. Gunning. If the  
9 company doesn't want to acknowledge a central fact, that's not  
10 a problem for me. Here's what I'm asking: The government's  
11 position is that the corporation conspired to make offers to  
12 doctors. And so the question I ask you, does the company admit  
13 the facts as recited by Ms. Carmody relative to the conspiracy  
14 to make this offer to physicians? And the facts that she  
15 recited are the ones I just mentioned, that this meeting was  
16 held at the Boston Harbor Hotel. That's part of what she  
17 said. A meeting -- sales were not going well, the meeting was  
18 held at the Boston Harbor Hotel, regional directors were  
19 invited, six regional directors -- I'll let you consult with  
20 your lawyer if you want to, then I'll tell you what I want you  
21 to hear from me.

22 MR. GUNNING: I'm sorry, I'm being distracted.

23 THE COURT: You consult and tell me when you're  
24 ready.

25 (Mr. Gunning conferred with counsel.)

1 THE COURT: Okay, sir.

2 MR. GUNNING: So let me give this a try.

3 Serono Laboratories also agrees that it and at  
4 least one company employee conspired to make payments in the  
5 form of a free trip to Cannes, France for physicians.

6 THE COURT: Okay. Thank you, sir.

7 MR. GUNNING: Thank you.

8 Ms. Carmody, do you see any reason why I should not  
9 take the plea of the corporation?

10 MS. CARMODY: No, I do not.

11 THE COURT: Mr. Depippo, do you see any reason why  
12 I should not take the plea of the corporation?

13 MR. DEPIPPPO: No, your Honor.

14 THE COURT: To these two counts?

15 MR. DEPIPPPO: No, your Honor.

16 THE COURT: All right. Mr. Gunning, please stand.

17 THE CLERK: Mr. Gunning, Serono Laboratories has  
18 been named in two counts in an information charging in count  
19 one conspiracy to introduce into interstate commerce, with  
20 intent to defraud and mislead, adulterated medical devices in  
21 violation of Title 18 United States Code 371; and in count two  
22 with conspiracy to offer to pay illegal remuneration to health  
23 care providers in violation of Title 18 United States Code  
24 section 371.

25 How do you plead to counts one and two of the

1 information, guilty or not guilty?

2 MR. GUNNING: Guilty.

3 THE COURT: It is the finding of the Court that  
4 Mr. Tom Gunning is an officer of the defendant corporation  
5 Serono Laboratories, Incorporated and that the board of  
6 directors of that corporation empowered him to waive indictment  
7 of the corporation of the two charges set forth in the  
8 information; that Mr. Gunning is -- was likewise authorized by  
9 the directors of the corporation to enter a plea of guilty to  
10 the two counts of the information; and that the corporation is  
11 financially able to pay the fine set forth in the plea  
12 agreement between the United States and the corporation; that  
13 the corporation is aware of the nature of the charges in the  
14 information and the consequences of pleading guilty to those  
15 charges; and, finally, that the plea of guilty that Mr. Gunning  
16 has entered on behalf of the corporation is a knowing and  
17 voluntary plea supported by an independent basis in fact  
18 containing each of the essential elements of each of the  
19 offenses charged in the information.

20 I will determine that the corporation may be found  
21 guilty of these two offenses. Acceptance of this plea,  
22 however, I will await information that I receive in the  
23 specific sentencing phase.

24 So let's proceed to the sentencing phase.

25 I normally ask, but I don't think it's really

1 necessary in this case, whether you, Ms. Carmody, have seen the  
2 presentence report.

3 MS. CARMODY: I have, your Honor.

4 THE COURT: Mr. Depippo, have you seen it?

5 MR. DEPIPPPO: Yes, your Honor.

6 THE COURT: And have you discussed it with the  
7 corporation?

8 MR. DEPIPPPO: I have, your Honor.

9 THE COURT: And specifically with Mr. Gunning?

10 MR. DEPIPPPO: I have, your Honor.

11 THE COURT: Let me take a moment, first, to thank  
12 our splendid probation office generally and particularly  
13 Ms. Sinclair, who has worked on this presentence report.

14 This was not an easy report to do. I see lots of  
15 presentence reports. Ms. Sinclair has worked with me in lots  
16 of criminal cases and has prepared many, many splendid  
17 presentence reports; but the work involved in this one was  
18 enormous, and so I want to take a moment to thank her  
19 particularly and the probation office for the fine work that  
20 has gone into preparing this presentence report.

21 I want to thank Ms. Sinclair in particular for the  
22 help she's giving me in understanding the presentence report,  
23 to the extent I have any understanding of it -- let me say I  
24 have some understanding of it. As you know, I started off  
25 getting the numbers wrong. But after so many numerals, I'm

1 lost. Math was not my best subject; arithmetic was not my best  
2 subject, so whatever fault there is in my getting these numbers  
3 mixed up in the beginning of this proceeding is my fault. But  
4 I want everybody to know that our probation office has done a  
5 magnificent job here. Ms. Sinclair has done a wonderful job  
6 putting it all together and particularly in explaining to  
7 somebody who is as dense as I am about these matters.

8 So I want to say that before we begin.

9 Let me then recite what the guidelines provide in  
10 this case, starting with the offense level computation.

11 What page is that?

12 PROBATION OFFICER: 46.

13 THE COURT: The guideline manual applicable to this  
14 case is the manual in effect at the time of the commission of  
15 the offense; that is to say, the manual of November 1, 2001.  
16 The probation department has determined that these guidelines  
17 are more beneficial to the corporation with respect to the loss  
18 calculation and the number of victims than the guidelines --  
19 the current guidelines or the guidelines at the time of  
20 sentencing.

21 On the basis of the 2001 guideline manual, the  
22 probation officer, using the procedures for determining  
23 guidelines organizations, including the culpability score  
24 computation, the probation officer has determined that the  
25 total culpability score of this corporation in these

1 circumstances is six, taking account the offense level  
2 computation of both of the two counts of conviction.

3 The culpability score of six results in a fine  
4 multiplier of 1.2 at the minimum level and 2.4 at the maximum  
5 level, and a statutory maximum of \$228,224,000.

6 All right. Have I stated that correctly as far as  
7 the United States is concerned, Ms. Carmody?

8 MS. CARMODY: Yes, your Honor.

9 THE COURT: Mr. Depippo, have I stated that  
10 correctly as far as the corporation is concerned?

11 MR. DEPIPPPO: Yes, your Honor.

12 THE COURT: All right. Now, are there objections  
13 to the culpability score at all? I guess I stated it  
14 correctly, but I suppose I specifically should ask if there are  
15 objections.

16 Does the government have any objection?

17 MS. CARMODY: No, your Honor.

18 MR. DEPIPPPO: Not to this Court.

19 THE COURT: I'm sorry, sir?

20 MR. DEPIPPPO: Not to this Court.

21 THE COURT: You have objection to something?

22 MR. DEPIPPPO: No, your Honor. We have no  
23 objections to the presentence report that need to be resolved  
24 by the Court.

25 THE COURT: That's fine

1 All right. Then let me proceed to state that the  
2 fine range as determined by the parties on this plea is  
3 \$136,935. The fine --

4 MR. DEPIPPPO: Judge, I'm sorry, it's \$136 million.

5 THE COURT: I told you.

6 Thank you. Don't let me do that again. Somebody  
7 stop me.

8 The guideline fine range as determined by the  
9 parties in accordance with their agreement is \$136,936,000 to  
10 \$2,868,800 is the range. And the parties have agreed that the  
11 fine to be paid by the corporation is \$136,936,000.

12 Have I stated that correctly at long last,  
13 Ms. Carmody?

14 MS. CARMODY: Yes, you have, your Honor. I just  
15 want to make one point. In fact, I think the parties agree on  
16 this, that the fine range I think has to be capped with a  
17 statutory maximum.

18 THE COURT: Yes. I should have said the range is  
19 \$136,936,000 to \$273,868,800. There's a statutory cap of  
20 \$228,224,000.

21 MS. CARMODY: That's correct, your Honor.

22 THE COURT: So the range in effect is \$136,936,000  
23 to \$228,224,000.

24 MS. CARMODY: That's correct, your Honor.

25 THE COURT: Okay.

1 Correct, Mr. Depippo?

2 MR. DEPIPPPO: Yes, your Honor.

3 THE COURT: Okay. Now, the parties have agreed  
4 that the fine should be the low end of the guideline range, and  
5 I won't recite the number again because I've said it correctly  
6 once and I don't want to mess it up.

7 The special assessment, mandatory special  
8 assessment on the two counts of conviction is \$800. There is a  
9 guideline range of probation of one to five years, and the  
10 parties have agreed that no probation is appropriate.

11 Have I stated that correctly, counsel?

12 MS. CARMODY: Yes, your Honor. And just to explain  
13 to the Court the reason, the company has agreed as part of the  
14 global resolution to enter into and has entered into a  
15 corporate integrity agreement with the Office of Inspector  
16 General for the Department of Health and Human Services; and  
17 that term is at least five years. And that oversight would be  
18 essentially more, actually, than I think a probation officer  
19 could do, and is more appropriate in these circumstances.

20 THE COURT: I think that's right.

21 We come now to the question on whether I can accept  
22 this plea on the basis of this agreement, and I have the  
23 question that I raised earlier in the proceeding having to do  
24 with the failure of the parties' agreement to take -- well,  
25 that's not an accurate statement. I'm sorry, Ms. Carmody and



1 Mr. Depippo. I was going to say the failure to take into  
2 account the individuals, and I appreciate that you took them  
3 into account. That would be an inaccurate statement.

4 I understand that the position of the parties to be  
5 that the complications of a restitution program for the  
6 individuals outweigh -- or the value of the global arrangement  
7 that the parties have entered into substantially outweighs the  
8 omission, any consequence of omitting any provision for the  
9 individual victims. Have I stated at that correctly?

10 MS. CARMODY: That's correct, your Honor. That's  
11 our position.

12 THE COURT: Okay. Mr. Depippo, can you speak to  
13 this question? Because it's -- if I am correct that some 9,000  
14 individuals -- and I'm primarily concerned with the individuals  
15 as opposed to the private corporate victims -- if there are  
16 9,000 individuals who may have been injured, isn't there  
17 something that might be done for those 9,000 that does not  
18 unreasonably burden the parties in administering the program?

19 MR. DEPIPPPO: Judge, a couple of things.

20 I mean, first, you know, there's a substantial  
21 portion of the restitution award in this case that relates to  
22 civil theories that are outside of counts one and count two.

23 THE COURT: I understand that.

24 MR. DEPIPPPO: And as part of that global civil  
25 settlement, with respect to those theories, the company has not

1 admitted to any liability. And so -- I mean, as an initial  
2 matter, there certainly will be, you know, a question as to  
3 whether those people have suffered any harm or any loss at  
4 all. And I think that there -- secondly, there would be a  
5 mechanism whereby -- and, in fact, is a mechanism whereby any  
6 harm would be redressed; and that is to say -- I'm not handling  
7 it, I'm not fully up to speed, but I'm well aware there is a  
8 civil suit that has been filed that purports to be a class  
9 action suit at least -- and as I understand it, it is filed on  
10 behalf of those that are the non-Medicaid payees of this drug.  
11 And so it seems to me that not only are there all of the  
12 complications, but there is also an alternative forum under  
13 which anyone who has been harmed can seek compensation.

14 THE COURT: I'm surprised I didn't think about the  
15 class action mechanism.

16 All right. I think you have addressed my problem,  
17 because, as I say, I am satisfied that the private insurers can  
18 take care of themselves; and oddly enough, Mr. Depippo -- not  
19 oddly enough for him, oddly enough for me, I didn't think of  
20 it, that there is a forum and the mechanism for the  
21 individuals, and that is a class action. Class action isn't  
22 easy, but it may be the best mechanism for any person who  
23 thinks of himself or herself injured by the company as a result  
24 of this scheme, because there will be a judicial, as  
25 distinguished from an administrative or alternative dispute

1 resolution, mechanism available to such person.

2           There is one thing, however, that it seems to me  
3 that should be -- and I just want to put this on the table, and  
4 maybe I don't have to do this, because maybe the fact of this  
5 plea and the fact of this global settlement will become public  
6 knowledge; just because of the size and of the nature of it, it  
7 will become public knowledge, but my thought had been that  
8 there might some means by which the company could communicate  
9 directly with people who may have been injured by providing  
10 information for physicians who prescribed the drug pursuant to  
11 this -- during the time of this conspiracy, a notice in the  
12 doctor's office, for example, so that people know that if they  
13 have claims, that they can make those claims before any statute  
14 of limitation runs.

15           What about that?

16           MR. DEPIPPO: Judge, as I understand it, when the  
17 plea agreement was announced in October, it was done at the  
18 highest levels, including the Attorney General of the United  
19 States. It received much fanfare in the media, and there has  
20 been, if you will, a public dissemination of these proceedings.

21           THE COURT: What does the United States think about  
22 that, Ms. Carmody?

23           MS. CARMODY: Well, your Honor, on October 17th,  
24 Attorney General Gonzales did make the announcement of the  
25 global resolution, including the government's agreement to

1 plead guilty in this case.

2           It did receive a lot of newspaper coverage, so that  
3 individuals, particularly physicians who may have been  
4 prescribing the drug, would have received or been able to  
5 access the information with respect to this.

6           THE COURT: If they happened not to be watching TV  
7 that day or didn't read the newspaper, they don't know.

8           I guess I need to ask you, Ms. Carmody, as a  
9 representative of the United States whether what I've just  
10 suggested is so fractious to this understanding that I  
11 shouldn't think about it any further?

12           MS. CARMODY: I'm not sure that it fractures the  
13 understanding, your Honor; but I think it's certainly  
14 something -- I know that we have considered in the context of  
15 our obligations with respect to the victims of the offense.

16           I think that certainly all the Medicaid agencies  
17 are aware of it, all the insurers are aware of it. With  
18 respect to physicians, physicians are aware of this case.

19           THE COURT: Well, you mean they're aware of it  
20 because there's been a newspaper -- other publicity about it.

21           MS. CARMODY: I think it's more than that, your  
22 Honor. In my experience in the investigation the number of  
23 physicians who are physicians who would prescribe this drug are  
24 not a lot in terms of all of the physicians in the United  
25 States. They're usually infectious disease doctors or doctors

1 who specialize in treating AIDS patients. That is a very small  
2 medical community in the context of the whole medical community  
3 of the United States. So that those doctors are very well  
4 connected with respect to issues such as this.

5           There are a lot of AIDS activists and AIDS -- there  
6 are several and very vocal groups of advocates for patients  
7 with AIDS and HIV who have been -- in fact, one was a relator  
8 in one of the civil actions in California, so that those AIDS  
9 activist groups are very well aware of that settlement and take  
10 on the role of advising patients who may be out there.

11           THE COURT: Is there some nationally recognized  
12 single or two or three --

13           MS. CARMODY: Advocacy groups.

14           THE COURT: Advocacy groups, I'm thinking about  
15 something like the Muscular Dystrophy Association -- I don't  
16 mean -- a group like that for people who are HIV and AIDS  
17 infected. Is there a group like that? There must be.

18           MS. CARMODY: There are regional groups, your  
19 Honor, for sure. And they're very activist groups,  
20 particularly, for example, in California, New York, Florida,  
21 some of the major payers for this drug.

22           I don't know of any one national agency, there must  
23 be, and we can certainly -- I mean, even with respect to the  
24 government's obligation, we could notify that -- whatever  
25 groups, major groups that we could identify. That would be not

1 be a burdensome task I would think.

2 THE COURT: I think that as part of this  
3 arrangement, and before I can accept the arrangement, and I  
4 want to add a provision, which I should tell you, Mr. Gunning,  
5 when I add it you will have the opportunity to withdraw this  
6 plea, but I want to add a provision that requires the  
7 cooperation with the United States and particularly with the  
8 United States attorney's office in this district in  
9 disseminating information -- I think if you tell me this will  
10 be sufficient -- to appropriate advocacy organizations  
11 throughout the United States about the proceedings here, that  
12 there has been a plea of guilty to these counts, there is a  
13 global settlement. That's all you need to say. Explain what  
14 the plea is, what the global settlement seeks to accomplish in  
15 some manner. I think if the parties will agree to this, I can  
16 agree to this plea, but I do think that I want -- ideally I'd  
17 like it to go to all of these 9,000 people, but since there's  
18 some difficulty in deciding who those 9,000 are -- isn't that  
19 the problem? You don't know who the 9,000 are?

20 MS. CARMODY: We have not -- I don't know that we  
21 can identify them specifically. We have tried. I've actually  
22 had agents try to make some kind of a list to notify, that's  
23 how we came up with the numbers that we do, but we know that  
24 our list is woefully inadequate, your Honor; and I wouldn't  
25 pretend to represent to the Court that I have an absolute list

1 of patients.

2 We have numbers from company documents. Part of  
3 the issue with AIDS patients is there's an awful lot of privacy  
4 concerns.

5 THE COURT: Of course.

6 MS. CARMODY: So that we may not have names of  
7 patients; and, in fact, in many instances, even when we got  
8 patient records to review, names were not identified.

9 I think that we can manage -- and I haven't had a  
10 chance to talk to Mr. Depippo and Mr. Gunning yet, but with  
11 respect to -- I know our obligations under the victim/witness  
12 statute we have ways to do a dissemination of information. So  
13 if we need to identify -- what I'm concerned about is what the  
14 Court considers appropriate or sufficient.

15 THE COURT: Well, you're right. I haven't been  
16 very specific, because I don't know how to be specific about  
17 this.

18 You told me a minute ago that the medical community  
19 regularly treating AIDS patients is relatively small.

20 MS. CARMODY: When I say relatively small, I think  
21 it's about --

22 (Discussion off the record.)

23 MS. CARMODY: -- 50,000.

24 MR. DEPIPPPO: It's a close-knit group, and they  
25 stay aware of developments.

1           As you know with AIDS, there's a new development  
2   you know every other day. It's not like some of these other  
3   diseases. And so they are -- I think that they're fairly  
4   characterized as a group of physicians that stay on top of  
5   things.

6           THE COURT: Well, one group of physicians I wonder  
7   can be those physicians who -- do we know who those physicians  
8   are who --

9           MS. CARMODY: The company has lists of physicians  
10   that prescribe this drug. There's absolutely no question about  
11   that, your Honor.

12          THE COURT: For purposes for which the government  
13   claims were unlawful.

14          MS. CARMODY: Yes.

15          THE COURT: Why don't we use that list and send  
16   this information to those physicians?

17          MS. CARMODY: To those physicians?

18          THE COURT: To those physicians.

19          MS. CARMODY: Rather than advocacy groups?

20          THE COURT: And advocacy groups.

21          MR. GUNNING: Your Honor, I feel that my authority  
22   is limited by what the board of directors has considered.

23          THE COURT: I certainly understand that.

24          MR. GUNNING: So I don't feel that I could make  
25   that kind of commitment on behalf of the company.



1 I do -- we would not have an objection if the  
2 government went with its press releases to the advocacy groups.

3 THE COURT: Here's what I would like to do,  
4 Mr. Gunning. I understand your position. Why don't I take a  
5 recess until sometime next week, and you can consult, see if  
6 you can get that authority. Because I want that done.

7 I will accept this plea if I can get that done. If  
8 I can get the communication to the advocacy groups of the  
9 doctors that the company has pleaded guilty and there has been  
10 this global settlement -- and you show me what it is you're  
11 going to tell me, and then I can be satisfied that the people I  
12 think who have been -- who individually have been harmed know  
13 about it, and they can take whatever action they want to take.

14 MS. CARMODY: Your Honor, may I have a moment to  
15 consult? But I think we can do that in the U.S. Attorney's  
16 Office.

17 THE COURT: The government will undertake this?

18 MS. CARMODY: I'd like to confirm that, but I think  
19 we might be able to.

20 If I may just have a moment to confer.

21 THE COURT: I'll take five minutes, a recess, and  
22 you confer.

23 MS. CARMODY: Thank you.

24 THE COURT: And if the government will undertake  
25 that responsibility -- understand I don't know who the advocacy

1 groups are, but you can find out; and I want the information  
2 from the company to you as to whom the doctors were.

3 I'll take five minutes and you can tell me whether  
4 you can do it. We can wrap this up today.

5 MS. CARMODY: Thank you, your Honor.

6 THE COURT: Thank you.

7 (Recess taken.)

8 THE COURT: Ms. Carmody, what can you --

9 MR. DEPIPPPO: Your Honor, may I address the Court?

10 THE COURT: Yes.

11 MR. DEPIPPPO: Judge, I want to put on the record  
12 what I think should satisfy the Court to conclude these  
13 proceedings today, and I've had discussions with the  
14 government; and that is, that the government and the company  
15 will work together to identify and agree on the prescribing  
16 physicians and appropriate AIDS advocacy groups to whom the  
17 company will send a notice of the global settlement and this  
18 plea.

19 THE COURT: Okay. That satisfies me.

20 I need to know how I implement this in terms of the  
21 sentencing. There's no term of probation, and so I -- maybe  
22 it's enough that I have this representation on the record, and  
23 that will be sufficient --

24 MR. DEPIPPPO: Judge, it's our view that is  
25 sufficient as long as the government concurs on the record.

1 THE COURT: Let me ask my expert here to my left.

2 PROBATION OFFICER: It seems to me that it could be  
3 sufficient, your Honor, because since it could have otherwise  
4 been incorporated in the plea agreement as part of their other  
5 agreements. But I'm not certain.

6 MS. CARMODY: Your Honor, we do could it by way of  
7 an addendum to the plea agreement.

8 THE COURT: That would be sufficient. All right.  
9 And since I am agreeing to accept this plea on the conditions  
10 set forth in the plea agreement, if that is added to the plea  
11 agreement, that will be a way to implement this added  
12 provision.

13 Mr. Gunning, if you'll stand, please. And thank  
14 you and Mr. Depippo and Ms. Carmody for taking the few minutes  
15 it took to satisfy me by adding that provision.

16 MR. GUNNING: No problem.

17 THE COURT: Now that you have added the provision,  
18 I should formally ask whether with the condition that I've  
19 added to -- that I insist be added to the plea agreement, does  
20 the company wish to withdraw its plea?

21 MR. GUNNING: No.

22 THE COURT: All right.

23 Then, Ms. Carmody, do you see any reason why I  
24 should not impose sentence?

25 MS. CARMODY: No, your Honor.

1 THE COURT: Mr. Depippo.

2 MR. DEPIPPPO: No, your Honor.

3 THE COURT: Pursuant to the Sentencing Reform Act,  
4 Mr. Gunning, and having considered the sentencing factors  
5 enumerated at Title 18 United States Code section 3553(a) and  
6 the plea agreement of the parties, as modified in the way we  
7 have just discussed on the record, it is the judgment of the  
8 Court that the corporation, Serono Laboratories, Inc., shall  
9 pay to the United States a fine of \$136,936,000. That fine  
10 shall be paid within seven days of the imposition of this  
11 sentence.

12 The fine is to be continued to be paid until the  
13 full amount, including interest, has been paid. And by that I  
14 mean, if it's not paid within that seven days, those interest  
15 penalties will continue to accrue.

16 It's further ordered that Serono Corporation shall  
17 comply with the terms of the Rule 11(c)(1)(e) plea agreement as  
18 modified --

19 MR. DEPIPPPO: Just for the record, that's Serono  
20 Laboratories, Inc.

21 THE COURT: What did I say?

22 MR. DEPIPPPO: You said Serono Corporation.

23 THE COURT: Thank you.

24 It's further ordered that the defendant, Serono  
25 Laboratories, Inc., shall comply with the terms of the

1 Rule 11(c)(1)(e) plea agreement as modified today and the  
2 settlement agreement entered into by the parties, including,  
3 but not limited to, the payment to the United States and  
4 participating -- Medicaid participating states collectively the  
5 sum of \$567,065,000 together with interest as set forth in  
6 paragraph one of the settlement agreement.

7 It is further ordered that the defendant, Serono  
8 Laboratories, Inc., shall pay the United States a required  
9 special assessment of \$800, which shall be due and payable  
10 immediately.

11 Are there any questions of anyone? Of me from  
12 anyone?

13 MR. GUNNING: No.

14 MS. CARMODY: No, your Honor.

15 THE COURT: Let me advise -- no question.

16 Let me advise the corporation through you,  
17 Mr. Gunning, that the corporation has the right to appeal this  
18 conviction if the corporation finds there's some fundamental  
19 defect in these proceedings not waived by the corporation's  
20 guilty plea.

21 The corporation also has a right to appeal the  
22 sentence to the extent that right has not been modified or  
23 waived by the corporation in the plea agreement.

24 Any appeal that the corporation wishes to file must  
25 be filed within ten days of judgment being entered in this

1 case.

2 Is there anything further, counsel, and  
3 Mr. Gunning?

4 MR. GUNNING: No.

5 THE COURT: If there's nothing further, then thank  
6 you very much for your cooperation for getting this matter  
7 settled.

8 We are adjourned.

9 (Court adjourned at 1:15 p.m.)

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11 CERTIFICATION

12 I certify that the foregoing is a correct  
13 transcript of the record of proceedings in the above;entitled  
14 matter to the best of my skill and ability.

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19 \_\_\_\_\_  
Debra M. Joyce

\_\_\_\_\_ Date

20 Official Court Reporter

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